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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,516	09/21/2005	Hans W. Schmid	2923-708	2283

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ROTHWELL, FIGG, ERNST & MANBECK, P.C.  
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WASHINGTON, DC 20005

EXAMINER
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MERCIER, MELISSA S

ART UNIT	PAPER NUMBER
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1615

NOTIFICATION DATE	DELIVERY MODE
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08/31/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

### Office Action Summary

**Application No.**

10/533,516

**Applicant(s)**

SCHMID, HANS W.

**Examiner**

MELISSA S. MERCIER

**Art Unit**

1615

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 and 20-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SI/88)
- Paper No(s)/Mail Date 5-2-05, 9-21-05, 8-28-07, 4-16-08, 4-28-08
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_



**DETAILED ACTION**

***Election/Restrictions***

Applicant's election of Group II, Claims 14-19, which have been rewritten as claims 20-25, in the reply filed on July 1, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-13 have been withdrawn from consideration. After further consideration of the election of species requirement, the Examiner has withdrawn the requirement.

***Priority***

Applicants claim of priority as a continuation of PCT/EP03/12097 filed on October 30, 2003, which is a continuation in part of Application 10/353,056 filed on January 29, 2003.

***Information Disclosure Statement***

Receipt of the Information Disclosure Statements filed on May 2, 2005, September 21, 2005, August 28, 2007, April 16, 2008, and April 28, 2008 is acknowledged.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-25 rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

M.P.E.P. § 2163 states, "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention...one must define a compound by 'whatever characteristics sufficiently distinguish it'. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process."

While the specification describes a species of the instantly claimed melatonin derivatives at p. 2, it does not describe a sufficient number of species as to convey possession of the entire genus encompassed by melatonin derivatives. Applicant has not provided adequate written description for the term melatonin derivatives with the exception of those specifically disclosed on page 2.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pierpaoli et al. (US Patent 4,746,674) in view of Matsumoto (US Patent 5,637,606) and further in view of Hanada et al. (US Patent 5,656,264).

Pierpaoli discloses a method of treating the skin and/or scalp of a human host by the administration of a melatonin composition in order to improve the cosmetic or physical appearance of the skin and/or scalp (abstract). The composition is disclosed as being topically applied to the skin (column 1, lines 8-11). The composition is used for the rejuvenation of partially degenerated hair follicles through the use of melatonin compounds, homologues, and derivatives (column 1, lines 20-21).

Regarding claim 21, the composition can be used for the treatment of drug induced or toxic alopecia (column 11, lines 40-43).

Regarding claims 22-23, the disclosure of humans encompasses both men and women.

Regarding claims 24-25, the relative concentration of melatonin is  $10^{-4}$  to 1% of an ointment (column 12, lines 63-65). It is additionally disclosed that the amount of melatonin administered can be altered based on the individual and the specific needs of that individual (column 7, lines 42-45).

Pierpaoli does not disclose the use of ginkgo biloba or biotin.

Matsumoto discloses a composition for preventing hair loss and promoting hair development and cures alopecia (Abstract). The compositions are applied topically to the scalp of male and female patients (column 3, lines 62-68). Matsumoto discloses the mechanism of the occurrence of hair loss is a direct result of a lowering of functions in trichogen cells. Ginkgo is disclosed as an activating agent for hair roots and trichogen cells (column 1, lines 52-68).

The combination of Pierpaoli and Matsumoto does not disclose the use of biotin.

Hanada disclosed a preparation for promoting hair growth and exhibits an excellent effect of promoting hair growth or curing alopecia (Abstract). Hanada discloses vitamins, such as biotin, have been used for activating enzymes of hair matrix cells to promote the synthesis of hair (column 1, lines 33-38).

It would have been obvious to one of ordinary skill in the art to have incorporated biotin into the formulation of Pierpaoli and Matsumoto in order to active the enzymes of the hair matrix cells to promote hair growth.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated the ginkgo of Matsumoto and the biotin of Hanada into the composition of Pierpaoli since both components are known to stimulate hair growth. It has been held that combinations of two or more compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (1960). As the court explained in Crockett, the idea of combining them flows logically from their having been individually taught in prior art. Therefore, since each of the references teaches melatonin, biotin, and ginkgo are effective ingredients in compositions for the treatment of hair loss, it would have been obvious to combine them with the expectation that such a combination would be effective in promoting hair growth. Thus, combining them flows logically from their having been individually taught in prior art.



***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is (571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/  
Examiner, Art Unit 1615

/MP WOODWARD/  
Supervisory Patent Examiner, Art Unit 1615